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| 10/590,300 | 06/21/2007 | Eric Thor Fossel | S1509.70037US01 | 7179 |
| 23628 | 7590 | 05/24/2010 | EXAMINER | |
| WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 | | | | TREYGER, ILYA Y |
| ART UNIT | | PAPER NUMBER | | |
| 3761 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/590,300 | FOSSEL, ERIC THOR | |
| | Examiner | Art Unit | |
| | ILYA Y. TREYGER | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 March 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 1,5,6,11,13,17,18 and 24-26 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2-4,7-10,12,14-16,19-23 and 27-29 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 August 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 2-4, 7-9, 12, 14-16 and 19-22 are amended.
2. Claims 1, 5, 6, 11, 13, 17, 18 and 24-26 are canceled.
3. Claims 2-4, 7-10, 12, 14-16, 19-23, and 27-29 are examined on the merits.

Response to Arguments

Applicant's arguments with respect to claims 4 and 20 have been considered but are moot in view of the new ground(s) of rejection.

4. With respect to claims 2, 10, 16 and 23, Applicant's arguments are based on the amendment made to the claims (See rejection below).

Claim Objections

5. Claim 3 is objected to because of the following informalities: claim 3 depends on claim 1 that has been canceled. In a purpose for examination claim 3 is interpreted as depending on claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3, 4, 7-10, 12, 14, 15, 19-23 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Falk et al. (US 5,824,658).

9. In Re claim 4, Fossel discloses the method comprising an act of:

applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the skin covering the breast is a selected area of skin, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

With regard to limitation "for a period of time sufficient to reduce sagging", since any medical treatment takes time, any medicine intended for medical treatment is necessarily capable of being applied for a period of time sufficient for treatment, i.e. reducing sagging.

Fossel does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Falk teaches the method of treating the skin of the breast (col. 12, line 1) by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Fossel the step of rubbing a

cream into the skin, as taught by Falk in order to improve therapeutic effect to the treatment (Falk, col. 12, line 16) and increase absorption of the cream.

In Re claims 3 and 19, Fossel discloses the method wherein the delivery vehicle is a cream (P. 1, [0015], ln. 1-2).

10. In Re claim 7, Fossel discloses the method wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what reads on "at least 5%" as claimed.

11. In Re claims 8 and 21, Fossel discloses the method wherein the delivery vehicle comprises the water or the oil (P. 1, [0015], ln. 7).

12. In Re claims 9 and 22, Fossel discloses the method fully capable to be repeatable (P. 1, [0015], ln. 1-3).

13. In Re claim 10, Fossel discloses the claimed invention discussed above, as applied to claim 9, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin between 2 and 30 times, inclusively, within a time period of about 30 days.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time range and overall duration of treatment, since the overall duration of the medical treatment by local action compositions and the rate of application of said compositions depend of the type of skin disease, degree of the skin lesion, and degree of the positive reaction of the patient, and therefore is the matter of routine experimentation what lies within the routine skill in the art.

14. In Re claim 12, since Fossel discloses the concentration of nitric oxide donor L-arginine of 12.5% (P. 1, [0015], ln. 3) as claimed, this amount of arginine is fully capable of producing the claimed function, i. e. act for at least about 3 hours, as per claim 12.

15. In Re claim 14, 15, 27, and 28, Fossel discloses the method wherein the ionic salt comprises sodium chloride, magnesium chloride, or choline chloride (P. 1, [0015], ln. 4-7), and their combined amount is 10% as per claims 15 and 28.

16. In Re claim 20, Fossel discloses the method comprising an act of:
applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, for a period of time sufficient for treatment fully capable for sagging skin treatment, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

Fossel does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Falk teaches the method of treating the skin of the breast (col. 12, line 1) by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15).

The rationale of obviousness rejection discussed above in claim 4 is incorporated herein in its entirety.

21. In Re claim 23, Fossil discloses the claimed invention discussed above, as applied to claim 22, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin after between about 8 hours and about 48 hours after the act of applying the delivery vehicle.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time repeating range because the treatment time repeating range depends of the skin resistance level, which can vary from patient to patient, and therefore is the matter of optimization.

17. In Re claim 29, Fossil discloses the method comprising an act of:
applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, for a period of time sufficient for treatment fully capable for sagging skin treatment, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

Fossil does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Falk teaches the method of treating the skin of the breast (col. 12, line 1) by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15).

The rationale of obviousness rejection discussed above in claim 4 is incorporated herein in its entirety.

18. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossil (US 2003/0028169) in view of Falk et al. (US 5,824,658), and further in view of Nakata et al. (US 5,332,758).

Fossil in view of Falk disclose the claimed invention discussed above, as applied to claim 4, but does not expressly disclose the method wherein the sagging is determined using viscoelasticity.

Nakata teaches that it is known to use Skin Viscoelasticity Test for skin diseases diagnostics (See Col. 17, ln. 9-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossil/ Falk with the determination of sagging skin, as taught by Nakata, because such modification would provide the most accurate diagnostic of the specific disease prior the therapeutic treatment.

19. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossil (US 2003/0028169) in view of Falk et al. (US 5,824,658), and further in view of Marty (US 4,702,913).

Fossil in view of Falk disclose the claimed invention discussed above, as applied to claim 4, but do not expressly disclose the method wherein the nitric oxide donor comprises one or more of a polysaccharide-bound'nitric oxide-nucleophile adduct, a N-nitroso-N-substituted hydroxylamines, a compound containing a sulphydryl group and a NO donor group, 1,3-(nitrooxymethyl)phenyl-2-hydroxybenzoate, a gel comprising a nitrite salt and an acid, S-

nitrosothiols, a nitrite, a 2-hydroxy-2-nitrosohydrazine, a substrate for nitric oxide synthase, a cytokine, an adenosine, bradykinin, calreticulin, bisacodyl, phenolphthalein, or endothelein.

Marty teaches that it is known to use adenosine in the cosmetic compositions (See Col. 2, ln. 42-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossal/ Falk with the use of adenosine, as taught by Marty, because such modification would improve cosmetic or/and therapeutic effect, since adenosine promotes the release of the nitric oxide radical.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761